K014057

MAR 8 2002

510(k) SUMMARY
ASCLEPION-MEDITEC AG
DermaStar Er:YAG Laser System

This 510(k) summary of safety and effectiveness for the ASCLEPION-MEDITEC AG DermaStar Er: YAG Laser System is submitted in accordance with the requirements of SDMA 1990 and follows Office of Device Evaluation Guidance concerning the organization and content of a 510(k) summary.

Applicant:	ASCLEPION-MEDITEC AG
Address:	Goeschwitzer Strasse 51-52 07745 Jena, Germany
Contact Person:	Dr. Dirk Colditz Vice President Operations and International Regulatory Affairs
Phone: Fax: e-mail:	+49 3641 220 501 +49 3641 220 502 ctz@asclepion.com
Preparation date:	September 2001
Device name:	DermaStar Er: YAG Laser System
Common Name:	DermaStar
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology (21 CFR 878.4810) Product code: GEX – Laser instrument, surgical, powered Panel: 79
Legally marketed:	Dermablate Er: YAG Laser System (K980361) MCL 29 Dermablate Er: YAG Laser System (K964128)
Description:	The DermaStar Er: YAG Laser System is an Erbium:YAG laser with a wavelength of 2.94μm. It consists a laser enclosure and fiber optic delivery system (including hand piece).
Intended Use:	The DermaStar Er: YAG Laser System is intended for coagulation, vaporization, ablation or cutting of soft tissue (skin) in dermatology, plastic surgery (including aesthetic surgery), oral surgery, and ophthalmology (skin around the eyes).

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Comparison to:	The specifications of the DermaStar are the same as or very similar to those of legally marketed lasers such as Dermablate Er: YAG Laser System (K980361) and MCL 29 Dermablate Er: YAG Laser System (K964128)
Performance data:	None. The specifications and intended uses of the DermaStarEr:YAG laser system are the same or very similar to those of claimed predicate devices. Because of this, performance data were not required.
CONCLUSION:	The DermaStar Er: YAG laser system is substantially equivalent to legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 8 2002

Asclepion-Meditec AG
c/o Mr. William Kelley
Asclepion-Meditec, Inc.
23832 Via Monte
Coto De Caza, CA 92708

Re: K014057
Trade/Device Name: DermaStar Er:YAG Laser System
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: November 27, 2001
Received: December 10, 2001

Dear Mr. Kelley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K014057

Device Name: *DermaStar Er:YAG Laser System*

Indication For Use:

The DermaStar is intended for coagulation, vaporization, ablation or cutting of soft tissue (skin) in dermatology, plastic surgery (including aesthetic surgery), oral surgery, and ophthalmology (skin around the eyes)

The laser system DermaStar is restricted to sale to or use by licensed professionals in the United States.

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K014057

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)